

REMARKS

The Office Action

Claims 72-90 are pending. Claims 74-80 stand rejected for indefiniteness. Claims 72-90 stand rejected for lack of enablement and obviousness-type double patenting over U.S. 2006/0252791 (hereafter “Bondy”). Claims 77-78 stand further rejected for anticipation by Grazul et al. (Natural Products Letters 1994, 5:187; hereafter “Grazul”), U.S. Patent No. 5,723,492 (hereafter “the ‘492 patent”), U.S. Patent No. 5,719,306 (hereafter “the ‘306 patent”), and WO 2004/005286 (hereafter “Neyts”). Claim 79 stands further rejected for obviousness over WO 2004/067516 (hereafter “Cardozo”).

Amendments to the Claims

Claims 72 and 79 have been amended. Claims 73-78, 80, 82-85, and 87-89 have been cancelled. New claims 91-125 have been added. The amendments to claim 72 find support in original claim 2. The amendments to claim 79 find support in original claim 56. New claims 91-113 find support in original claims 5, 6, 8, 9, 11, 12, 18, 21, 25, 26, 27, 28, 29, 35, 37-44, and 46 and page 12, lines 9-10, and new claims 114-118 find support in original claims 57-60 and 62. New claims 119-125 find support in original claims 61-64 and page 15, lines 12-15. The claims have also been amended to correct typographical and clerical errors. No new matter has been added.

Rejections under 35 U.S.C. § 112, second paragraph

The Office has rejected claims 76, 78, and 80 for indefiniteness for referring to the examples in the specification. These claims have now been cancelled, and the rejection is moot.

The Office has rejected claims 74-75 and 79 for indefiniteness for the limitations relating to element “Q.” The Office has requested clarity on the definition of Q and “linking group,” recited in these claims.

The purpose of the definiteness requirement is to ensure that “the scope of the claim is clear to a hypothetical person possessing the ordinary skill in the pertinent art” (M.P.E.P. § 2171). Furthermore, M.P.E.P. § 2173.02 states:

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In addition, “[b]readth of a claim is not to be equated with indefiniteness” (M.P.E.P. § 2173.04).

Here, claim 79 recites many moieties as pendant from the imidazo[4,5-c]pyridine core (formula C). R³ is shown in formula C, and this group may be substituted with at least one R¹⁷. R¹⁷ is defined as the group M-Q-. Q is either a bond connecting M and R³ or is a linking group, i.e., a divalent moiety, connecting M and R³. When a linking group, the claim further requires Q to have 1 to 10 atoms, optionally substituted with R¹⁹. The specification further provides examples of such groups, alkylene (page 22, lines 14-15) and alkylene with oxy or thio ester (page 23, lines 14-20). Specific Q groups are also shown in the compounds described in the specification: -CH₂O- (page 57), -SO₂CH₂- (page 57), -CHCH- (page 58), -NSO₂- (page 58), -O- (page 58), -C(O)- (page 59), -C(O)C(O)- (page 65), -NC(O)- (page 67), and -S- (page 68). In addition, the specification states that Q is a spacer group and is not critical (page 22, lines 14-15); accordingly, no further limitations are required in the claim. The term “linking group” is also commonly used in the art to refer to spacer groups. Indeed, a search of the PTO database yields thousands of applications that recite “linking group” in the claims. Finally, one skilled in art could easily determine whether a particular compound fails within the scope of the present claim based on the express limitations of the claim, the examples provided, and the common usage of

the term in the art. Nothing more is required, and the rejection should be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

The Office has rejected all pending claims for lack of enablement on one of two bases. The first basis is the recitation of “linking group” in claims 74-75 and 79. The second basis is the recitation of “solvates” in the claims.

For the first basis, the Office asserts that the claims are enabled for some linking groups, e.g., alkylene, but not others. Other than this conclusion, the Office provides no legal or factual basis for the rejection. M.P.E.P. § 2164.04 states:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In addition, any rejection for enablement requires that the Office make factual findings with respect to the *Wands* factors and provide specific technical reasons to support the rejection (M.P.E.P. § 2164.01(a)). In this case, the Office has not provided any factual findings or technical reasons to support the rejection. In addition, as discussed above, the specification, claims, and prior art provide guidance on the meaning of the term linking group. The application also provides examples of compounds including various linking groups and their synthesis. Based on this information, one skilled in the art could make compounds with various linking groups and use them according to the invention. The claims are thus enabled, and the rejection should be withdrawn.

For the second basis, the claims have been amended to delete reference to the term “solvate,” and the rejection is now moot.

Obviousness-type double patenting

Applicants acknowledge the rejection of the present claims for obviousness-type double patenting over Bondy. In contrast to the Office’s position, Bondy is not an issued patent. In fact, the application was abandoned, although a continuation application is pending (12/022,557). Accordingly, at best, the rejection is provisional.

The present application also has an earlier filing date than Bondy and its continuation. Applicants submit that the present claims are now allowable, and, as such, the provisional rejection should be withdrawn under M.P.E.P. 804(I)(B)(1).

Rejections under 35 U.S.C. § 102

Claims 77-78 stand rejected for anticipation by Grazul, the ‘492 patent, the ‘306 patent, and Neyts. In order to be anticipatory, a reference must teach every limitation of the claims (M.P.E.P. § 2131). None of the cited reference meet this requirement with respect to the amended claims.

With respect to Grazul, the compound provided by the Office is a imidazo[4,5-c]pyridinium compound, having a positively charged, quaternary nitrogen atom. Independent claims 72 and 79 do not allow for a quaternary nitrogen atom in the imidazo[4,5-c]pyridine core. In addition, the compound of Grazul has a hydrogen atom at the location corresponding to R¹ in the present claims. Amended claims 72 and 79 also do not allow R¹ to be hydrogen. Thus, the present claims do not encompass the compound of Grazul, and the rejection should be withdrawn.

With respect to the ‘492 and ‘306 patents, the compound provided by the Office also includes a hydrogen atom at the location corresponding to R¹ in the

present claims. As amended claims 72 and 79 do not allow R¹ to be hydrogen, this rejection may also be withdrawn.

With respect to Neyts, the compounds recited by the Office are those with R³ substituted by R¹⁷ being pyridinyl or 5-chloro thienyl. Amended claims 72 and 79 now exclude pyridinyl and 5-chloro thienyl as possibilities for R³ substituted with R¹⁷, and this rejection may also be withdrawn.

Rejections under 35 U.S.C. § 103

The Office has rejected claim 79 for obviousness over four compounds disclosed in Cardozo. The basis for the rejection is that compounds of the present invention are structural isomers or homologs of the compounds disclosed in Cardozo. Applicants submit that the Office has inadvertently mischaracterized the structural relationship between the Cardozo compounds and those instantly claimed.

First, the compounds encompassed by the present claims are not structural isomers or homologs of the compounds in Cardozo. As is explained in M.P.E.P. § 2144.09, isomers are compounds having the same radicals in physically different positions on the same nucleus, and homologs are compounds that differ regularly by the successive addition of the same chemical group. The Office admits that the compounds of Cardozo would require the addition of a group to be covered by the claims. Accordingly, the present compounds are not isomers of the compounds of Cardozo. With respect to homology, modification of the compounds of Cardozo to produce an R¹⁷-R³-X group as required by the present claims would require insertion of a methylene group between two heterocycles. Insertion of an unrelated group in the middle of a molecule is not the successive addition of the same group. Thus, the present compounds are not homologs of those disclosed in Cardozo.

In addition, all four compounds from Cardozo are *tetrahydro* imidazo[4,5-c]pyridine compounds having two double bonds in the core structure and

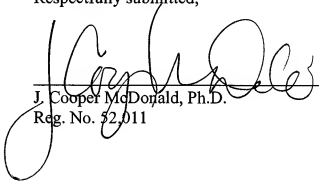
hydrogen atoms at the location corresponding to R^1 . In contrast, the compounds of claim 79 require four double bonds. And, as is discussed above, claim 79 has been amended so that R^1 is not hydrogen. Thus, the compounds of the present invention exhibit at least three distinguishing features compared to the Cardozo compounds, and, even if there were a reason to insert a methylene group within the compounds of Cardozo, doing so would not yield a compound of the invention. This rejection may also be withdrawn.

CONCLUSION

Applicants submit that the claims are now in condition for allowance, and such action is respectfully requested. Enclosed in a petition to extend the period for reply for one month. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 6/11/09


J. Cooper McDonald, Ph.D.
Reg. No. 52,011

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045